510(k) SUMMARY
ORTHOVITA PEEK SPACER

JAN 2 5 2011

November 19, 2010

510(k) Number (if known): K101171

1. **Contact Person**

Catherine Moffa, M.S.
Director, Regulatory Affairs
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Malvern, PA 19355
(t) 610-640-1775 – (f) 610-640-1714

2. **Device Name and Classification**

Product Name:	ORTHOVITA PEEK SPACER
Classification Name:	Intervertebral body fusion device with bone graft, cervical
Common or Usual Name:	Intervertebral body fusion device
Classification Panel:	Orthopedic
Regulation Number:	888.3080
Device Class:	Class II
Product Code:	ODP

3. **Predicate Device(s)**

Choice Spine's Cervical Interbody Spacer and System (K091531)

4. **Device Description**

ORTHOVITA PEEK SPACER is a cervical interbody fusion device designed to be inserted within the intervertebral disc space in order to provide structural stability and act as an aid in spinal fixation. Machined from medical grade PEEK-OPTIMA®, the device is trapezoidal in shape with a hollow frame to accept autogenous bone graft. ORTHOVITA PEEK SPACER is available in a range of heights and geometries to accommodate individual pathologies and anatomical conditions.

5. **Indications for Use**

ORTHOVITA PEEK SPACER is indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-C7. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. ORTHOVITA PEEK SPACER should be used with a commercially available supplemental spinal fixation system. ORTHOVITA PEEK SPACER should also be packed with autograft prior to implantation. Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with ORTHOVITA PEEK SPACER.

6. **Performance Data**

The below list of preclinical bench testing was performed on the ORTHOVITA PEEK SPACER. The acceptance criteria of all tests were met.

- Static and dynamic axial compression, and static and dynamic torsion in accordance with ASTM F2077, *Test Methods for Intervertebral Body Fusion Devices*
- Static subsidence testing in accordance with ASTM F2267, *Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression*

7. **Substantial Equivalence**

Information within this submission supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Orthovita, Inc.
% Ms. Catherine Moffa, M.S.
Director, Regulatory Affairs
45 Great Valley Parkway
Malvern, Pennsylvania 19355

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Re: K101171
Trade/Device Name: Orthovita Peek Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 20, 2010
Received: January 21, 2011

Dear Ms. Moffa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

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Prescription Use (Part 21 CFR 801 Subpart D)	___X___	AND/OR Over-The Counter Use (21 CFR 807 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101171